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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,738	01/26/2001	Christopher Perry	S-50061P1	6030

22847 7590 05/20/2003

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1638

DATE MAILED: 05/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/770,738	Applicant(s) Perry
	Examiner Medina Ibrahim	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Feb 19, 2003
 - 2a) This action is FINAL. 2b) This action is non-final.
 - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1-44 and 46-49 is/are pending in the application.
 - 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
 - 5) Claim(s) 1-5, 8-13, 16-22, and 25-28 is/are allowed.
 - 6) Claim(s) 6, 7, 14, 15, 23, 24, 29-44, and 46-49 is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some* c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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DETAILED ACTION

Applicant's response filed 2/19/03 in reply to the Office action mailed 09/10/02 and amendment B have been entered. Claim 45 has been cancelled. Therefore, claims 1-44 and 46-49 are pending and are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All rejections and objections not set forth below have been withdrawn.

Claim Objections

Claim 46 is objected to for depending upon cancelled claim 45. Treatment of the claim in the instant office action, in the interest of compact prosecution, does not relieve Applicants of the responsibility to respond to this objection.

Claim Rejections - 35 USC § 112, 2nd paragraph

Claims 6-7, 15, and 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the same reasons as set forth in the last Office action. Applicant's arguments filed in response of 2/19/03 have been considered but are not found persuasive.

Claim 6 remains rejected because the claims which claim 6 depends from do not recite a "male sterile" plant and is unclear how the plant of claim 6 resulted to be male sterile.

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Applicant argues that since production of male sterile plants is standard in the art and is described in pages 2 and 3 of the specification, the plant of claim 2 can be made male sterile and is definite. Applicant urges that rejection be withdrawn (response, pg 5).

Applicant's argument is not persuasive because while production of male sterile plants are known in the art, the rejected claim is not drawn to a method of making the plant of claim 2 a male sterile plant or a male sterile plant produced by said method. The claim is directed to a male sterile plant , otherwise having all of the morphological and physiological characteristics of the plant of claim 2. Because male sterility can be the result of many different physiological and morphological changes, it is unclear how the two plants, one non-male sterile and other male sterile, share the same morphological and the physiological characteristics. The metes and bounds of the claim is unclear. The rejection is maintained.

Claim 7 and dependents 15, 31-36 remain rejected because of the recitation of a "gene transferred trait".

Applicant argues that there is no lack of clarity of a " gene transferred trait" because the instant specification provides a discussion with citations and publications that describe genes that have been transformed into plants and subsequently bred into elite lines, as well as the germoplasm into which a gene has to be transferred.

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Applicant's arguments are not persuasive because while the specification describes genes transferred into maize inbred line by breeding or by genetic transformation methods, the specification does not define what a "gene transferred trait" is, and therefore, the phrase is open to a variety of interpretations. It is unclear if a gene transferred by backcrossing and/or by genetic transformation, or by any other means is intended. In addition, while the claims are read in light of the specification, the limitations of the specification are not read into the claims. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 112, Enablement

Claims 7 14-15, and 37-41 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reasons of record as set forth in the Office action mailed 09/10/02. Applicant's arguments filed in response of 2/19/03 have been considered but are not found persuasive.

Applicant argues that claims drawn to maize plants of the inbred line NP2073 comprising a single gene transferred trait introgressed by backcrossing are enabled because methods for introgressing a transgene into genetic background of a plant are standard in the art. Applicant cites two articles, Principles of Plant Breeding, 2nd edition and an internet overview article to support the enablement of gene

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edition and an internet overview article to support the enablement of gene introgression. Applicant finally questions the relevance of the Hunsperger, Eshed and Kraft cited by the Examiner in the last Office action to support the unpredictability in the transfer of a single gene by backcrossing. In page 7 of the response, 1st and 2nd full paragraphs, Applicant argues that Hunsperger publication teaches work in petunia and not corn, and that Kraft article is not on point because breakup of lineage disequilibrium will occur after a number of backcross generations. Applicant urges that the rejection be withdrawn (response, pages 6-9).

The Examiner maintains the rejection is proper given that the claims are drawn to maize plants and seeds of the inbred NP2171 comprising a single gene transferred trait or transgenes, F1 hybrid plants/seeds produced by crossing the exemplified inbred plant with another unknown maize plants, and NP2171-derived maize plant or maize plants having an ancestor of said NP2171 . Applicant has provided no evidence to support the conclusion that the introgression of a single gene into different genetic backgrounds is routine in the art. The cited reference, "Principles of Plant Breeding" describes backcrossing method as a tool for improving homozygous varieties and inbred lines of outcrossing species with superior characteristics but deficient in one or few specific characteristics. The overview article describes the process of producing genetically engineered plants for use in backcross breeding with an elite line to combine the desired trait of the elite line with the transgene into a single line. However,

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the enablement rejection is based on unpredictability in transferring a single gene trait into an inbred line by backcrossing without changing other desired unique morphological and physiological characteristics of the inbred. Applicant has not provided a publication or a prior art where a single gene has been successfully transferred into an inbred corn plant without disrupting the other characteristics or genotype of the plant. Since Applicant has not demonstrated via working examples that a single gene trait can be transferred from genetic background of an elite into the inbred line NP2171 while retaining the unique genotypic and phenotypic characteristics of the inbred, and since the prior art does not amend the deficiency, one skilled in the art who is willing to practice the claimed invention is left with trial and error experimentations considered to be undue.

While the state of the art supports that transformation of a plant by genetic engineering and subsequent breeding of the transformed plant with another elite are powerful tools to transfer a single gene into a plant to improve or create a desired agronomic trait in said plant, the transfer of a single gene by backcrossing between an inbred corn and a different plant of even from the same species is not routine.

With respect to Hunsperger and Kraft references, the Examiner maintains that the references are applicable given the lack of practical examples (not theory) available in the art regarding introgression of a single gene trait into corn genetic background,

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physiological characteristics of the inbred. Contrary to Applicant's arguments, if phenotypic variations occur in Applicant's inbred NP2171 because of linkage disequilibrium, the end product can still contain the selected single gene expressing its product, however, the inbred may not retain its unique morphological and physiological characteristics. Phenotypic variations occur as a result of genotypic variations.

Therefore, in view of the reasons discussed above and in the last Office action, the claimed invention is not enabled.

Written Description

Claims 7-8, 15, 23-24, 29-44, and 46-49 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the Office action mailed 09/10/02. Applicant's arguments filed 2/19/03 have been considered but are not deemed persuasive.

Applicants' arguments are basically the following: 1) based on *Enzo Biochem v. Gen-Probe Inc*, the deposited seed of NP2171 meets the written description requirement of the claimed invention, namely F1 hybrid plants and seeds and NP2171-derived plants. 2) F1 hybrid and NP2171 plants are adequately described because their genome contain "NP2171 traits" which sufficiently distinguishes them from other

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their genome contain "NP2171 traits" which sufficiently distinguishes them from other maize plants. Applicant cites *In re Hayes Microcomputer* and *Purdue Pharm L.P.* case laws to support his position.

Firstly, while the deposit of the seed of the inbred line NP2171 is sufficient to provide written description for F0 generation plants/seed, the deposit is insufficient to provide written description for any hybrid plant or seed including F1 generation or those derived from the inbred line NP2171. Applicant has not indicated that any hybrid progeny derived from NP2171 will also be deposited. Secondly, since the specification does not describe what "NP2171 traits" are, the phenotypic or the genotypic characteristics of a maize plant having NP2171 traits is not known. Thirdly, the claimed plants are produced by crossing NP2171 plant with unknown breeding partners, and since each parent contributes a set of alleles and these two sets of alleles interact in a variety of ways (influenced by the environment) to determine the phenotype of the progeny, one cannot predict how the genes of the known parent NP2171 will affect the phenotype of the F1 hybrid. The specification, page 5, lines 20-30, discusses the complexity of inheritance and states "the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes. These new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the action of the breeder". The specification also states "it is not known how the

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desired genotype would react with the environment". Therefore, it is likely that hybrid plants/seeds produced from each cross with NP2171 may be genetically distinct. Plants derived from the hybrid plants crossed with unknown plants would have less genetic material from NP2171. Therefore, absent further description, the deposit of the seed of the inbred line NP2171 is insufficient to provide written description for any hybrid plant or seed including F1 generation or those derived from the inbred line NP2171.

Regarding claims encompassing "transgenes" and "introgressed gene", while the specification describes methods of transforming plants with a transgene and breeding technologies, the issue here is written description, not an enablement. NP2171 plants/seed further comprising genes that confer unknown phenotypes, and a method for using said plants/seed are not described. The phenotype or the genotype of a plant with unspecified transgene, introgressed gene , or single gene trait, is unknown. Applicants should note that claims 9-14 meet the written description requirements because the plant comprises a single transgene with specific phenotype that is well-known in the art.

Regarding the case law *In re Hayes*, the instant application does not present an analogous situation because technology is different and that plant breeding is an unpredictable art as compared to the art of how to program a microprocessor to perform the necessary function. Because a plant breeder cannot predict the genotype, how the genotype will interact with environment or the resulting phenotypes of the

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developing lines, except perhaps in a very broad and general fashion, more detailed description of resultant plants are required to demonstrate possession. In this application, Applicant has not described other than F0 plant/seed and a method for using said F0 plant/seed. Note NP2171-derived maize plant of claim 42 is not adequately described because the two traits recited in the claims are insufficient to provide written description for the plant. What makes unique the NP2171 line is the combination of genes and traits. The combination is lost in subsequent generations. Therefore, one cannot distinguish the claimed maize plants from other maize plant. The *Eli Lilly* case, as stated on page 12 of Applicant's response, states that "all that is required under 35 USC 112, 1st paragraph, is a description that distinguishes the claimed invention from other materials". The Examiner believes that *Eli Lilly* presents an analogous set of facts. Therefore, Applicant's arguments are not persuasive. The rejection is maintained.

Claim Rejections - 35 USC § 102/103

Claims 42 and 49 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mies et al (US Patent 5, 792, 906(A)). This rejection is repeated for the reasons of record as set forth in the Office action mailed 09/10/02. Applicant's arguments filed 2/19/03 have been considered but are not deemed persuasive.

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Applicant's arguments are basically the following: 1) since Mies et al reference does not anticipate or make obvious over the maize inbred line NP2171 of claim 1, it is impossible that the same prior art anticipates or makes obvious the plants of claims 42 and 49. The Examiner responds that, unlike claims 42 and 49, the plant of claim 1 has been described with unique characteristics that distinguish from the prior art maize plant. In addition, it should be noted that the claims are rejected under 102/103 because the Examiner cannot determine whether the prior art plant possesses the unrecited features of claim 42. The Examiner does not have sufficient facts to determine that the maize plants and seeds are inherently not the same. Applicant's arguments do not provide clear and convincing evidence that the prior art would neither anticipate nor render obvious the claimed invention. Absent such evidence, the rejection is maintained. See *In re Thorpe* cited previously.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

Claims 1-5, 8-13, 16-22, and 25-28 are allowed.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00 AM to 5:00 PM and Wednesday-Thursday from 9:00AM to 3:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

May 13, 2003

mai



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